## Remarks

The final Office Action dated August 11, 2006 has been reviewed and the following remarks are made in response thereto. In view of the following remarks, Applicants respectfully request reconsideration of this application and timely allowance of pending claims. Upon entry of the instant amendment, claims 57-65 and 70-75 are pending. Claims 57, 58 and 60-63 are amended and claims 70-75 are new. Written support for the claim amendments, new claims and amendments to the specification are found throughout the specification and in the original claims, thus Applicants submit that no prohibited new matter has been added. Additionally, claims 66-69 were cancelled without prejudice or disclaimer to the subject matter claimed therein.

With regard to the amendment of claim 57, Applicants point out that the computer in the specification is defined by its ordinary meaning as "an electronic device that has the ability to store, retrieve, and process data, and can be programmed with instructions that it remembers. The physical parts that make up a computer (the central processing unit (*i.e.* processor), input, output, and memory) are called hardware" (definition of computer at <a href="https://www.techdictionary.com">www.techdictionary.com</a>) (copy of reference herein provided for Examiner's convenience). As such, Applicants' amendment to claim 57 clarifies that the processor conducts the comparison of gene expression profiles from a test sample to a reference in order to identify the presence or absence of BPH in the patent sample. Representative support for this claim amendment is located in the specification, example 9, page 30, lines 14-21.

## Rejections under 35 U.S.C. 112

Claims 57-69 were rejected under 35 U.S.C. 112 (first paragraph) for allegedly failing to comply with the written description requirement. The Examiner purported that the specification did not have adequate written description for a computer system comprising a <u>user interface</u> for entering information into a computer.

Without acquiescing to the merits of the Examiner's rejection, and solely to expedite prosecution of the instant application, Applicants have removed the term "user interface" from claim 57. Further, Applicants have cancelled claims 62-69 thereby rendering the rejection as to these claims moot.

Accordingly, Applicants respectfully request that the rejection of claims 57-69 under 35 U.S.C. 112 (first paragraph) be withdrawn.

Moreover, the Examiner maintained the rejection of claims 57-69 under 35 U.S.C 112 (first paragraph) for failing to comply with the written description requirement. The Examiner purported that

the specification did not disclose <u>software</u> for comparing data from a test and control sample in order to generate <u>a second data set</u>, which is indicative of the presence or absence of BPH. Applicants respectfully traverse the rejection.

Without acquiescing to the merits of the Examiner's rejection, and solely to expedite prosecution of the instant application, Applicants have amended claim 57 such that the recitation of a second data set and software has been removed. The amended claim clarifies that the reference expression profile is compared to a test sample in order to identify the presence or absence of BPH in the test sample (specification, example 9, page 30, lines 14-21). Further, Applicants have cancelled claims 66-69 thereby rendering the rejection as to these claims moot.

Last, claims 57-69 were rejected under 35 U.S.C 112 (first paragraph) for failing to comply with the written description requirement. The Examiner purported that the specification did not have adequate written description for a database or computer system comprising data from specific number of genes in a control sample.

Without acquiescing to the merits of the Examiner's rejection, Applicants have cancelled claims 66-69 thereby rendering the rejection as to these claims moot.

With respect to claims 57-65, Applicants respectfully traverse the rejection. Applicants point out that the instant specification provides that the expression levels of at least about 2, 3, 4, 5, 6, 7, 8, 9, 10 or more genes in any of Tables 1-6 may be detected. In a preferred embodiment, all of the genes in Tables 1-6 may be detected (specification, page 3, lines 26-27). To determine the differential expression of any of the genes in Tables 1-6 in a test sample, the expression must be compared to a control sample (hence the term differential expression). Such a comparison inherently requires that the genes in the test sample be compared to the same genes in the control sample. For instance, to determine differential expression of 100 genes from tables 1-6, the expression levels of these 100 genes in a test sample must be compared to the expression levels of these same 100 genes in a control sample. Given that the specification provides for the detection of at least about 2, 3, 4, 5, 6, 7, 8, 9, 10 or more, or all of the genes in Tables 1-6 in a test sample, these genes must be inherently detected in a control sample. As such, the specification provides for the detection of at least about 2, 3, 4, 5, 6, 7, 8, 9, 10 or more, or all the genes in Tables 1-6 in a control sample. Accordingly, Applicants respectfully request that the rejection of claims 57-69 under 35 U.S.C. 112 (first paragraph) be withdrawn.

## Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request reconsideration and timely allowance of the pending claims. A favorable action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of this application, she is invited to telephone the undersigned at her convenience.

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **constructive** petition for extension of time in accordance with 37 C.F.R. 1.136(a)(3).

Dated: November 13, 2006 Morgan, Lewis & Bockius LLP Customer No. 09629 1111 Pennsylvania Ave., N.W. Washington, D.C. 20004 202-739-3000 Respectfully submitted

Morgan, Lewis & Bockius LLP

Christopher J. Betti, Ph.D. Registration No. 56,890

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**Definition:** 

Computer Professionals for Social Responsibility

(CPSR). A public-interest alliance of computer scientists and others interested in the impact of computer technology on society. As concerned citizens, they direct public attention to critical choices concerning the applications of computing and how those choices affect society.

computer literate

Having a working knowledge of computers and software; does not imply extensive technical expertise.

computer phobia

Literally, fear of computers. Anxiety about learning to use computers, or not being able to learn successfully; often used simply to mean resistance to learning the new skills required by increasing use of computers in

the workplace.

computer aided engineering

(CAE) Using computers to help with engineering design

computer aided design

(CAD). In fields such as engineering and architecture, using computer graphics to do work that formerly would have been done with pencil and paper. CAD requires a high-resolution monitor and special

software.

computer

An electronic device that has the ability to store, retrieve, and process data, and can be programmed with instructions that it remembers. The physical parts that make up a computer (the central processing unit, input, output, and memory) are called hardware. Programs that tell a computer what to do are called

software.

Computer

The journal published by the IEEE (Institute of Electrical and Electronics Engineers) Computer Society.

Compaq Computer Corporation

A Houston, Texas major manufacturer and vendor of PC compatibles and PC servers, maker of the first PC

computer aided design &

drafting

(CADD). CAD systems with features added for drafting.

computer aided design/computer aided manufacturing

(CAD/CAM). A combination of CAD and CAM. For example, a designer creates a 3-dimensional representation of an object, with the help of the computer, and then the computer programs instructions for automated manufacture of the object

and controls the manufacturing process.

desktop computer

**Electronic Numerical** Integrator and Computer A computer that is small enough to sit on a desktop. (ENIAC) The first digital electronic computer,

developed by John Mauchly and J. Presper Eckert during World War II at the University of Pennsylvania and released in 1946. ENIAC was used for scientific research and weather prediction, among other things.

Computer Dealers Exposition

(COMDEX). A computer trade show, held in the spring in Atlanta, GA and in Las Vegas, NV in the fall. New releases of software and hardware are are often first

demonstrated at Comdex.

Computer Emergency Response Team

(CERT). An organization formed by DARPA in 1988 after the Internet worm incident. CERT watches for threats to Internet security, educates the public about

computer security issues, and conducts research to improve the security of existing systems. CERT issues advisories and provides 24-hour technical assistance in response to computer security emergencies.

Association of Personal Computer User Groups

(APCUG). A nonprofit organization dedicated to encouraging communication between user groups, and between user groups and vendors.

Apollo Computer, Inc.

A maker of high-performance workstations, and a pioneer in workstation networking. It became a division of HP in 1989.

Computer and Business Equipment Manufacturers Association

(CBEMA). A Washington, DC organization that develops standards for computers and business equipment worldwide.

Certificate in Computer Programming

(CCP). A certificate awarded by the Institute for Certification of Computer Professionals which indicates the bearer has passed an examination, and has some computer education or job experience.

computer aided software engineering

(CASE). The use of computers to help with the analysis, design, implementation or maintenance of software. Also called Computer Assisted Software Engineering.

computer assisted software engineering

(CASE). The use of computers to help with the analysis, design, implementation or maintenance of software. Also called Computer Aided Software Engineering.

computer geek

A person who is fanatically interested in computers. In the positive sense, the word can mean someone who is very knowledgeable about computers. In the negative sense, it implies someone who has few social skills, and is only comfortable communicating with computers.

computer games

Games played on the computer. Computer games may be played from a floppy disk or CD-ROM, by means of electronic mail, or online via BBS or Internet. There are single-player and multi-player games. The term is sometimes used to refer to those games that have a visual interface, as opposed to text-based games like RPGs and MUDs. Some popular computer games are DOOM, Wolfenstein, and Myst.

Computer Security Act

An act signed in January 1988 by President Reagan, establishing guidelines for the security and privacy of information in U.S. government computer systems, the training of federal employees in computer security practices, and the differences between computer security in defense-related and civilian agencies of

European Computer Manufacturers Association

(ECMA). An organization of computer manufacturers that helped with prestandardization work for OSI.

computer graphics

The creation, editing, or publishing of pictures by means a computer.

computer output microfilm printer

(COM printer). A page printer that produces a microimage of each page on photographic film.

computer aided language learning

(CALL). The use of computers in learning a language.

Apple Computer, Inc.

One of the largest personal computer manufacturers, located in Cupertino, California. The company was founded by Steve Jobs and Steve Wozniak, in a garage. The Apple II, released in 1977, became very popular for educational use. VisiCalc, the first computer spreadsheet, was designed for the Apple II. Another computer in the Apple line was the Lisa, introduced in 1983. In 1984, Apple released the first Macintosh computers. The graphical user interface and mouse of the Macintosh revolutionized personal computing, and Macintosh quickly became popular for desktop publishing. In the 1990s, Apple Computer,

IBM, and Motorola began working together to develop compatible products, and in 1994, the PowerMac came out. Based on the PowerPC microprocessor, it can run both Macintosh, DOS, and Windows applications. Other Apple products are the PowerBook laptops and the Newton personal digital assistant.

A computer whose central processing unit can process 32-bit computer

32 bits of information at a time.

A computer whose central processing unit can process 8-bit computer

8 bits of information at a time.

A computer whose central processing unit can process 16-bit computer

16 bits of information at a time.

computer programmer A person who writes instructions (programs) for

computers.

Computer Graphics Metafile (CGM). An ANSI standard format for exchanging

graphics files between applications, in both vector and

raster formats.

digital computer A computer that operates on data which is represented

as binary digits (0s and 1s). All commonly-used computers are digital. See analog computer, hybrid

computer.

analog - computer A computer that uses analog methods to process data.

An analog computer operates with numbers

represented by directly measurable quantities (such as temperature changes or voltages) which vary continuously, whereas a digital computer works with signals which are either on or off (binary 0 or 1). All ordinary computers are digital; analog computers are employed for special uses, such as robotics, where an experimental design can be tested in real time. Representing data in continuously variable physical quantities, in contrast to the digital representation of

data in discrete units (the binary digits 1 and 0). Analog systems handle information which is

represented by continuous change and flow, such as voltage or current. An analog signal is responsive to changes in light, sound, heat and pressure. Analog devices have dials and sliding mechanisms. Digital information, in contrast, is either on or off. An analog is a representation of a pattern by a similar pattern; for example, an analog clock represents the sun circling around the earth. An analog device converts a pattern such as light, temperature, or sound into an analogous pattern. An example is a video recorder, which converts light and sound patterns into electrical

signals with the same patterns. An analog signal such as a sound wave is converted to digital by sampling at regular intervals; the more frequent the samples and the more data recorded, the more closely the digital representation resembles the analog signal. Converting analog signals into digital makes it possible to preserve the data indefinitely and make many copies without

deterioration of quality.

Attached Resource Computer

Network

(ARCNET). A local area network (LAN) introduced in 1968 by Datapoint Corporation. It can connect up to 255 nodes in a star topology, using twisted pair or coax. ARCNET is a data link protocol and uses the

token passing access method.

computer conferencing Communication between people at different geographic locations by means of text and graphic messages sent

between interconnected computers.

computer crime A crime committed using a computer or data stored on

a computer.

Computer+Science Network

(CSNET). A large computer network, including universities, research labs, and some commercial enterprises. It originated in the United States, and has some members in other countries. CSNET merged with BITNET to form CREN.

computer program component

(CPC). A routine or module within a larger program.

computer generations

The development of computers began in the late 1940s and early 1950s with huge mainframes that used vacuum tube technology. The second generation of computers were built with discrete transistors, from the mid-1950s through the mid-1960s. Thirdgeneration computers were built using integrated circuits after the mid-1960s; during this time period, minicomputers were developed. The fourth generation of computers are the microcomputers which use largescale integration or very large-scale integration. The fifth generation of computers, beginning in the late 1990s, is expected to greatly expand the use of artificial intelligence. See also first generation computer, second generation computer, third generation computer, fourth generation computer, fifth generation computer.

brain-controlled computer

A computer that can be interfaced with the human brain. One example is a computer system that has been developed to enable totally immobile and speechless people to communicate. A device is implanted into the subject which reads neural impulses from the brain and translates the impulses to the movement of a pointer on the screen. For example, thinking of the left foot causes the mouse to move to the bottom left of the screen.

first generation computer

One of the original computers built in the late 1940s and early 1950s, using vacuum tube technology. One of these computers filled an entire room and had many operating stations. Examples include ENIAC, the Mark 1, and the IAS computer.

fourth generation computer

A computer built using large-scale integration (integrated circuits that contain more than 100 logic gates) or very large-scale integration (integrated circuits containing 10,000 or more logic gates). Microcomputers are fourth-generation computers.

fifth generation computer

The next generation of computers, beginning in the late 1990s, which will expand the use of artificial intelligence.

**IEEE Computer Society** 

The Computer Society of the Institute of Electrical and Electronics Engineers holds conferences on computers and technology, and publishes a journal called Computer.

Institute for Certification of Computer Professionals

(ICCP). An organization in Des Plaines, IL, U.S.A. that certifies computer professionals in many countries. Certification is given on the basis of tests, academic credit, and/or job experience. The different types of certification are: Associate Computer Professional (ACP), Certified Computer Programmer (CCP), Certified Data Processor (CDP), and Certified Systems Professional (CSP).

fuzzy computer

A computer that is designed to use fuzzy logic.

Intergraph Computer Systems

(ICS). A Huntsville, Alabama computer manufacturer. Intergraph develops, manufactures, sells, and supports computer systems for the Technical Desktop. Some products are Intel-based TD personal workstations, TDZ 3D workstations, servers, peripherals, and interactive computer graphics systems.

hybrid computer

A computer which is a combination of analog and digital computer systems. A hybrid computer uses analog-to-digital conversion and digital-to-analog conversion, and may input or output either analog or digital data. One use for these computers is in robotics. See analog computer, digital computer.

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